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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/042,508 | 01/08/2002 | Thomas O. Murdock | ARC 2452D1 | 7206 |

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ALZA CORPORATION
P O BOX 7210
INTELLECTUAL PROPERTY DEPARTMENT
MOUNTAIN VIEW, CA 940397210

EXAMINER

MICHENER, JENNIFER KOLB

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1762

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/042,508

Applicant(s)

MURDOCK, THOMAS O.

Examiner

Jennifer K. Michener

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-2 and 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haak et al. (5,993,435).

Haak teaches a method of forming an anhydrous reservoir layer for use in an electrode assembly of an iontophoretic delivery device (abstract; col. 12, line 54 and throughout). The delivery device is trans-dermal in nature and the electrode delivers a beneficial agent to the patient with the help of electrical energy (background). The reservoir layer (15, Figure 2) of Haak may be formed by solvent casting the beneficial agent matrix (col. 15, line 37) and adjoining to a hydrophilic polymer filtration membrane (paragraph

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bridging columns 8-9; 14 of Figure 2). Since both the reservoir layer and filtration membrane of Haak are solvent-casted (Example 1), a solvent must be present in the reservoir layer of Haak. Since Haak teaches an anhydrous reservoir layer, the solvent of Haak must be inherently removed from the filtration membrane after casting, as required by the claim.

While Haak does not specifically teach that the beneficial agent is "dissolved" in the solvent of his method during solvent casting, it is Examiner's position that it would have been obvious to an ordinary artisan to provide such a matrix for casting in the solution or dissolved form to provide uniformity of ingredients to the casted layer.

While Haak teaches the desire for the agent reservoir and the membrane to remain non-hydrated until use, some small amount of solvent may be present, such as water or non-aqueous solvents (col. 11, line 53 and col. 13, lines 1-5).

Regarding claims 5-6, Haak teaches the use of polysulfone or polyether sulfones as the filtration membrane (columns 8-9).

Solvent removal is equivalent to the "drying" step of claim 7. While Haak doesn't teach a method of drying or solvent removal, Examiner notes that ovens and freeze-dryers are well-known for their use in drying a coated substrate, both of which desiccate, or dry out, the coating. It would have been obvious to one of ordinary skill in the art desiring to

create an anhydrous reservoir layer from a solvent-containing reservoir layer to use a suitable drying process to remove solvent, such as an oven or freeze-dryer.

4. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haak in view of Huntington (6,057,374).

While Haak teaches that some solvent, such as water or non-aqueous solvents, may be present, he fails to teach which other solvents may be suitable in his electrode assembly.

Huntington also teaches providing an anhydrous drug reservoir layer to an iontophoresis device by solvent casting the drug with permeation enhancers such as ethanol in water (col. 3, line 54; col. 10, line 42; claim 12). Ethanol acts as a solvent along with the water.

Since Haak teaches water and other solvents suitably present in the reservoir layer of his electrode assembly and Huntington teaches water and ethanol in the reservoir layer of a similar electrode assembly, Huntington would have reasonably suggested the use of ethanol as a solvent in the method of Haak. It would have been obvious to one of ordinary skill in the art to use the teachings of Huntington in the method of Haak with the expectation of success since Huntington teaches the suitability of ethanol as a solvent in such a process.

While Huntington does not teach the use of isopropanol as a solvent, Haak teaches the use of solvents other than water and Huntington teaches the use of alcohols, with ethanol being merely exemplary. It is Examiner's position that the substitution of isopropanol, a similar, short-chained (C-3) alcohol for ethanol, a C-2 alcohol, would

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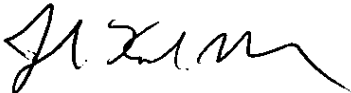
have been obvious and within the skill of an ordinary artisan. Given ethanol as an example, selection of iso-propanol from the broad class of alcohols would have been obvious to an ordinary artisan.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
June 10, 2004